

K051765

JUL 14 2005

NeuroLogica

**510(k) SUMMARY
For
NeuroLogica Corporation
NL3000 CereTom™ Computed Tomography System**

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

(1) Submitter: NeuroLogica Corporation
14 Electronics Avenue
Danvers, Ma, 01923

Establishment
Registration number: Not yet applied for

Contact person: Brahim Hadri
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Date this summary was prepared: June 1, 2005

(2) Device Name:

Proprietary or Trade Name: CereTom

Device Model: NL3000

Classification Name: Computed Tomography X-ray System

Product code: 90JAK

Device classification: Class II

Regulation number: 21 CFR 892.1750

(3) Predicate device:

The legally marketed devices to which substantial equivalencies are being claimed are as follows:

- Philips Tomoscan M/EG CT. This predicate device was cleared under pre-market Notification K964890.
- GE LightSpeed Ultra CT. This predicate device was cleared under pre-market Notification K000300
- Siemens SOMATOM Plus 4 with sliding Gantry Option. This predicate device was cleared under pre-market Notification K991600

(4) Device Description:

The NL3000 CereTom is a high resolution, 8 row, 32 cm bore, 25cm field of view, Computed Tomography System. The lightweight translating gantry consists of a rotating disk with a solid state x-ray generator, 3264-element solid state detector array, collimator, control computer, communications link, power slip-ring, data acquisition system, reconstruction computer, touch screen LCD display, power system, brushless DC servo drive system (disk rotation), and stepper drive system (translation). The power system consists of dry sealed batteries which provide system power while unplugged from the charging outlet. When plugged into an outlet the system charges the batteries with a line power drain of less than 1300 watts. The work station consists of a Sony Vaio laptop computer. The workstation software consists primarily of a certified off-the-shelf CT viewing system from a third party vendor. In addition the system has the necessary safety features such as emergency stop switch, x-ray indicators, interlocks, patient alignment laser, and 110 percent x-ray timer. It requires very little x-ray power in comparison to large bore systems to obtain equivalent CT image quality. The gantry has retractable 100mm diameter rotating caster wheels so the system can be moved easily to different locations.

(5) Intended Use:

The NL3000 CereTom is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 25cm field of view, primarily head and neck.



(6) Comparison of Technological Characteristics with the predicate device:

NeuroLogica Corporation believes that the NL3000 Computed Tomography System, for its intended use, is of comparable type in design, material, functionality, technology and is substantially equivalent to the following cleared predicate devices: Philips Tomoscan M/EG (also named ANATOM 2000, ref: K964890), GE LightSpeed Ultra, ref: K000300, and Siemens SOMATOM Plus4 with Translating Gantry option, ref: K991600

- **Material:** The CereTom uses similar material to the above listed scanners such as solid state detectors, x-ray generator, slip ring, data acquisition ICs, rotational bearing, and motion control systems. It also uses batteries and wheels similar in material to the Tomoscan M/EG.
- **Design:** The CereTom is similar in general design principle to all of the above listed CT systems. Specifically it is similar to the 1) Lightspeed in multi-slice (8 Row) image quality, 2) Tomoscan M/EG and Somatom Plus 4 as to the translating gantry (patient stays still while the gantry translates), and 3) Tomoscan M/EG as to batteries and wheels.

7) General Safety and Effectiveness Concerns:

All components of the NL3000 CereTom system subject to Federal Diagnostic Equipment Performance Standard and applicable regulations of 21 CFR Part 1020.30 and 1020.33 are certified to meet those requirements.

An initial report as per 21CFR Part 1002.10 will be filed with the Center for Device and Radiological Health (CDRH).

To minimize electrical, mechanical and radiation hazards, Neurologica adheres to recognized and established industry practices. The NL3000 CereTom system is designed to meet UL60601-1, IEC 60601-1 and EN 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety.



8) Conclusion

Based upon the above considerations, NeuroLogica Corporation believes that the NL3000 CereTom Computed Tomography System is of comparable type in design, material, functionality, technology and is, for its intended use, substantially equivalent to the following cleared predicate devices: Philips Tomoscan M/EG (also named ANATOM 2000, ref: K964890), GE LightSpeed Ultra, ref: K000300, and Siemens SOMATOM Plus4 with Translating Gantry option, ref: K991600. A product report, according to 21 CFR 1002.10, will be submitted to the FDA prior to first delivery of the NL3000 CereTom.

Use of the NL3000 CereTom does not result in any new potential safety risks. The equipment performs as well in its intended use as devices currently on the market.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2005

NeuroLogica Corporation
% Mr. Neil E. Devine, Jr.
Responsible Third Party
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K051765
Trade/Device Name: NL3000 CereTom
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography
x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 29, 2005
Received: June 30, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not known~~ K051765

Device Name: NL3000 CereTom

Indications for Use:

The NL3000 CereTom is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 25cm field of view, primarily head and neck.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051765

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